

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA et al. ex
rel. RAYBURN ALEX THOMPSON,

Plaintiffs,

v.

APOLLO PATH, LLC; et al.

Defendants.

Civil Action No. 3:20-cv-2917-D

**UNITED STATES' STATEMENT OF INTEREST
REGARDING DEFENDANTS' MOTION TO DISMISS**

The United States respectfully submits this Statement of Interest pursuant to 28 U.S.C. § 517 to address three arguments in the Defendants' Motion to Dismiss. ECF Nos. 54-55. Specifically, the United States contends that the causation standard under the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7(b), and the False Claims Act (FCA), 31 U.S.C. §§ 3729–33, does not require a showing that the kickback was a but-for cause of the submission of the false claim. Second, the United States contends that “remuneration,” as used in the AKS, can include compensation that is fair market value. Third, the United States contends that, if the requisite intent is present, the AKS prohibits paying volume-based sales commissions to independent contractors. The United States submits this statement of interest to ensure the correct interpretation of these three legal issues but does not take a position on any other arguments or issues raised in Defendants' Motion (including as to whether Relator's allegations satisfy the correct pleading standards).

I. The United States' Interest

Although the United States has not intervened in this *qui tam* action, it remains the real party in interest, entitled to the majority of any recovery that the Relator may obtain on the

United States’ behalf. *See* 31 U.S.C. § 3730(d); *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 934–35 (2009). The United States has a substantial interest in ensuring the correct application of the FCA because it is “the Government’s primary litigative tool for combatting fraud” against the public fisc. *United States ex rel. Aldridge v. Corp. Mgmt., Inc.*, 78 F.4th 727, 732 (5th Cir. 2023) (quoting S. Rep. 99-345, reprinted in 1986 U.S.C.C.A.N. 5266).

The United States likewise has an interest in ensuring the correct interpretation of the AKS because that statute plays a critical role in safeguarding the integrity of medical care paid for by Government health care programs. The AKS makes it a crime to “knowingly and willfully offer[] or pay[] any remuneration” in order to induce the recipient to “purchase, . . . order, or arrange for or recommend purchasing, . . . or ordering” goods or services “for which payment may be made in whole or in part under a federal health care program.” 42 U.S.C. § 1320a-7b(b)(2). In addition to criminal penalties, the AKS provides that “a claim that includes items or services resulting from” an AKS violation is “false or fraudulent” under the FCA. *Id.* § 1320a-7b(g).

II. AKS Framework and Background.

The AKS helps to protect the integrity of medical care by establishing that the government will pay only for items or services from providers who lack potential financial conflicts. Courts have long held that claims seeking reimbursement for items or services for which a kickback was offered or solicited are false or fraudulent under the FCA, because “[t]he Government does not get what it bargained for when a defendant is paid . . . for services tainted by a kickback.” *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011), *abrogated on other grounds by Universal Health Servs., Inc. v. United States*, 579 U.S. 176 (2016).

In 2010, Congress amended the AKS to state expressly that “a claim that includes items

or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of” the FCA. 42 U.S.C. § 1320a-7b(g). This amendment added a more direct way of establishing FCA liability for AKS violations. A sponsor explained that the amendment was meant to “strengthen[] whistleblower actions based on medical care kickbacks.” 155 Cong. Rec. S10,853 (daily ed. Oct. 28, 2009) (Sen. Kaufman). The amendment would clarify, the sponsor stated, “that all claims resulting from illegal kickbacks are ‘false or fraudulent,’ even when the claims are not submitted directly by the wrongdoers themselves.” *Id.*; see *United States ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 333 (S.D.N.Y. 2014) (discussing this legislative background).

III. Defendants Misstate the Causation Standard Under the AKS

Defendants assert that Relator’s Complaint should be dismissed because, in Defendants’ view, it did not plead that the alleged kickback was the but-for cause of the decision of the healthcare providers to make referrals of patient specimens to Apollo Labs and Arbor and thereby failed to plead plausible causation under the AKS. ECF No. 55 at 27. In making this argument, Defendants assert that to establish that a claim for payment includes items or services resulting from an AKS violation, a plaintiff must prove that the harm would not have occurred but-for the defendant’s conduct. *Id.* at 12. The United States respectfully submits that this standard—which has not been adopted by the Fifth Circuit—is incorrect because it is inconsistent with the structure and purpose of the AKS. See *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 98 (3d Cir. 2018) (rejecting “but for” standard and noting that sufficient link is established if “one of [defendant’s] claims sought reimbursement for medical care that was provided in violation of the [AKS]”); *Kester*, 41 F. Supp. 3d at 332 (rejecting “but for” causation standard because “there is no indication in either the law itself or the legislative history that Congress intended to narrow the scope of ‘falsity’ under the FCA when it amended the AKS to

add Section 1320a–7b(g)').

As an initial matter, the Court need not—and so should not—reach this issue because it does not have to determine the proper standard for causation under the AKS at the motion-to-dismiss stage. *See United States ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 665 (S.D. Tex. 2013), *aff'd sub nom. United States ex rel. Parikh v. Brown*, 587 F. App'x 123 (5th Cir. 2014) (“As a matter of pleading standards, [the Fifth Circuit in] *Grubbs* establishe[d] that Relators need not identify particular claims resulting from the kickback scheme.” (citing *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009))). At the pleading stage, the Court need only determine whether a relator has pleaded “particular details of a scheme to offer kickbacks in order to induce referrals, coupled with reliable indicia leading to a strong inference that claims based on such referrals were actually submitted.” *Id.* at 667 (citing *Grubbs*, 565 F.3d at 190); *see also United States ex rel. Everest Principals, LLC v. Abbott Labs., Inc.*, 622 F. Supp. 3d 920, 933 (S.D. Cal. 2022) (declining to resolve dispute over Section 1320a-7b(g)’s causation requirement where allegations sufficient at pleading stage to “adequately establish[] a ‘link’ between the kickback and the claim for reimbursement”).

Though this Court need not reach this causation issue, the majority of courts have rejected but-for causation under the AKS. *See Greenfield*, 880 F.3d at 98; *United States ex rel. Hueseman v. Pro. Compounding Centers of Am., Inc.*, 664 F. Supp. 3d 722, 741 n.4 (W.D. Tex. 2023) (“This Court is neither bound nor persuaded by the Eighth Circuit’s reasoning, which has been rejected by numerous courts.”); *United States ex rel. Fitzer v. Allergan, Inc.*, No. 1:17-CV-668-SAG, 2022 WL 3599139, at *10 (D. Md. Aug. 23, 2022); *Kuzma v. Northern Ariz. Healthcare Corp.*, 607 F. Supp. 3d 942, 957 (D. Ariz. 2022); *United States ex rel. Schroeder v. Medtronic, Inc.*, No. 17-2060-DDC-KGG, 2021 WL 4168140, at *23–24 (D. Kan. Sept. 14, 2021); *United States ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, No. 13-CV-3003, 2021 WL 101193, at *10–11 (D.

Minn. Jan. 12, 2021); *United States v. Teva Pharms. USA, Inc.*, No. 13 Civ. 3702 (CM), 2019 WL 1245656, at *23 (S.D.N.Y. Feb. 27, 2019); *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-CV-10601-IT, 2018 WL 1996829, at *6 (D. Mass. Apr. 27, 2018); *but see United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1052–53 (6th Cir. 2023); *United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 836 (8th Cir. 2022).

There are numerous reasons to reject but-for causation in the context of false claims arising from violations of the AKS. As one court observed in rejecting the *Cairns* causation analysis, the Eighth Circuit failed to consider powerful “contextual indication[s]” that Section 1320a-7b(g)’s causation standard is *not* but-for causation. *Fitzer*, 2022 WL 3599139, at *10. In addition, the AKS contains its own nexus requirement: Remuneration can support liability when it is solicited or received “in return for,” or offered or paid with the intent “to induce,” the provision of items or services or referrals to provide them. 42 U.S.C. § 1320a-7b(b)(1), (2). As its plain language makes clear, that standard does not limit AKS liability to situations where the desired outcome of the kickbacks actually materializes, much less where the kickback is the but-for cause of the outcome. *See Parikh*, 977 F. Supp. 2d at 665.

The limitation imposed by a but-for causation standard would also be inconsistent with the AKS’s animating principle, namely that financial conflicts make it impossible to trust a provider’s judgment—whether or not the conflicts can be shown to have actually altered the provider’s treatment choices. There is no discernible basis to believe that Congress, having imposed criminal liability for AKS violations *without* requiring but-for causation, meant to require that heightened showing to impose civil liability under the FCA for claims rendered false by AKS violations. *See Greenfield*, 880 F.3d at 96. Beyond its inconsistency with the basic purpose of the AKS, such a standard would significantly complicate the litigation of FCA cases based on AKS violations, requiring extensive efforts to disentangle the motivations of treating

physicians (who may not even be among the defendants) for every treatment decision or referral at issue (often numbering in the hundreds or thousands). And it would be inconsistent with the legislative history of § 1320a-7b(g), which makes clear that Congress enacted that provision to “strengthen[] whistleblower actions based on medical care kickbacks.” 155 Cong. Rec. S10,853.

These important “contextual” factors strongly suggest that Section 1320a-7b(g) does not impose a but-for standard. *See Burrage v. United States*, 571 U.S. 204, 212 (2014). There is a much more natural interpretation of “resulting from” in that provision. Remuneration can support liability under the AKS when it is solicited or received “in return for,” or offered or paid with the intent “to induce,” referrals or the provision of items or services. 42 U.S.C. § 1320a-7b(b)(1), (2). When the intended result of a kickback occurs, it makes sense to conclude that it “result[ed] from” the kickback within the meaning of § 1320a-7b(g), without an additional showing about what might have occurred absent the kickback.

Again, the Court need not resolve this statutory dispute here. The Fifth Circuit has held that Rule 9(b) “is context specific and flexible and must remain so to achieve the remedial purpose of the False Claim Act.” *Grubbs*, 565 F.3d at 190. Under binding Fifth Circuit precedent, a relator may survive a motion to dismiss “by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.” *Id.* Thus, the Court need not determine the applicable standard for AKS causation at this stage.

IV. “Remuneration” Need Not Exceed Fair Market Value

Defendants argue that Relator’s AKS claims are fatally flawed because Relator never claims that any sales representative was paid above fair market value, and thus, no unlawful remuneration was paid to them. ECF No. 55 at 13. Moreover, Defendants wrongly state that no

“remuneration” exists under the AKS if payment is made at fair market value. ECF No. 55 at 13. This argument misstates the law and is inconsistent with the language of the AKS.

The AKS does not expressly or implicitly reference fair market value as an element of the offense. 42 U.S.C. § 1320a-7b(b)(1)(B); *see also, e.g., Health Choice, LLC v. Bayer Corp.*, No. 5:17-CV-126 RWS-CMC, 2018 WL 3637381, at *14 (E.D. Tex. June 29, 2018); 56 Fed. Reg. 35952 (Jul. 29, 1991) (in using the term “remuneration,” Congress intended “to cover the transferring of anything of value in any form or manner whatsoever”). However, certain safe harbors do include requirements that remuneration be consistent with fair market value. *See, e.g.,* 42 C.F.R. § 1001.952(b)-(d). It would make no sense to require the United States or a relator to prove the absence of fair market value as part of their prima facie case, and then to have defendants prove the satisfaction of those same elements as part of an affirmative defense. In addition, the safe harbors that include those elements have additional requirements, thereby causing “only a small subset of such [fair market value] transactions” to be exempt from the AKS. *See United States v. Bay State Ambulance and Hosp. Rental Serv., Inc.*, 874 F.2d 20, 31 (1st Cir. 1989) (“Congress did not explicitly change the statute to exclude [from all AKS liability] reasonable payments for actual work done”).

Thus, courts repeatedly have rejected the argument made by Defendants here, recognizing that something of value can amount to improper “remuneration” under the AKS even if it is offered at market price. *See, e.g., Bay State Ambulance and Hosp. Rental Serv., Inc.*, 874 F.2d at 29-30 (rejecting argument that government “had to prove that the payments received were not reasonable for the actual work done”); *United States ex rel. Perri v. Novartis Pharms. Corp.*, Civ. No. 15-6547, 2019 WL 6880006, *13 n.14 (D.N.J. Feb. 21, 2019) (“I also find persuasive the government’s argument that there may be situations where an exchange is an illegal ‘remuneration’ within the meaning of the AKS, even though the exchange itself is for ‘fair

market value.”); *United States ex rel. Patel v. Catholic Health Initiatives*, 312 F. Supp. 3d 584, 596 (S.D. Tex. 2018) (“The presence of a legitimate business purpose for the arrangement or a fair market value payment will not legitimize a payment if there is also an illegal purpose.”); *United States ex rel. Boise v. Cephalon, Inc.*, No. 08-287, 2015 U.S. Dist. LEXIS 49341, at *26 (E.D. Pa. Apr. 15, 2015) (“I am also convinced that relators need not allege that speaker fees were provided at higher than market rates for similar speaking engagements in order to constitute kickbacks underlying a theory of FCA liability.”); *United States ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 678 (W.D. Pa. 2014) (“the crux of whether the [AKS] ... [is] violated” is whether the defendant “had the requisite intent to violate the statute,” namely, “whether the parties entered business arrangements in exchange for, or to induce, patient referrals”); *United States ex rel. Health Dimensions Rehab., Inc. v. RehabCare Group, Inc.*, No. 4:12CV00848, 2013 WL 4666338, at *5 (E.D. Mo. Aug. 30, 2013) (“Lack of fair market value, per se, is not an element the Government must provide.”); *see also* 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005) (explanation by HHS-OIG that “under the [AKS], neither a legitimate business purpose for the arrangement, nor a fair market value payment, will legitimize a payment if there is also an illegal purpose (i.e., inducing Federal health care program business)”).

Defendants’ contrary position is based on certain decisions in which courts have accepted defendants’ invitations to graft additional elements on to the AKS. *See, e.g., Bingham v. HCA, Inc.*, 783 F. App’x 868, 873 (11th Cir. 2019). Respectfully, for the reasons set forth above, those decisions are incorrect. The court in *Bingham*, for example, believed that compensation may confer “value” only if it exceeds the market rate for the services rendered. That analysis ignores the reality, persuasively explained by the First and Third Circuits, that “[g]iving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient.” *Bay State Ambulance & Hosp. Rental Serv.*,

874 F.2d at 29-30 (holding that “[t]he trial court did not err in not specifically instructing the jury that the government had to prove that the payments received were not reasonable for the actual work done,” as “[t]he gravamen of Medicare Fraud is inducement,”) (citing *United States v. Greber*, 760 F.2d 68, 71 (3d Cir. 1985) (“Even if the physician performs some service for the money received, the potential for unnecessary drain on the Medicare system remains. The statute is aimed at the inducement factor.”)).

Thus, to establish a violation of the AKS, it is sufficient that the plaintiff allege that the defendant (1) knowingly and willfully (2) offered, paid, solicited or received remuneration (3) to induce or in return for patient referrals. Even assuming that the compensation at issue in this case was fair market value (a factual question on which the United States takes no position here), such a finding would not be determinative of whether the AKS element of remuneration is met.

V. Volume-Based Sales Commissions To Independent Contractors Do Not Meet a Safe Harbor to the AKS

Defendants incorrectly argue that the AKS does not prohibit the payment of sales commissions to independent contractors based on the profitability of sales. ECF No. 55 at 9, 20. On the contrary, subject to certain exceptions, the AKS broadly prohibits paying someone to induce or in return for the use of a federally funded healthcare service. This may include the payment of volume-based commissions of salesman who are independent contractors. *See, e.g., United States v. Mallory*, 988 F.3d 730, 738 (4th Cir. 2021) (“[F]ederal appellate courts have frequently, and indeed invariably, upheld Anti-Kickback Statute violations based on commission payments to third parties.”).

The AKS prohibits knowingly and willfully offering or paying “remuneration” to any person “to induce such person” to either (A) “refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be” at least partially made by a federal healthcare program, or to (B) “purchase, ... order, or arrange for or

recommend purchasing ... or ordering” such items or services. 42 U.S.C. § 1320a-7b(b)(2). The statute similarly prohibits knowingly and willfully receiving remuneration “in return” for the same conduct. *Id.* § 1320a-7b(b)(1). This language, absent protection by an exception or safe harbor, unambiguously prohibits paying independent contractor salespeople to advocate for or facilitate the purchase of federally funded healthcare services.

The AKS’s broad language is no accident. In light of the broad language, Congress created numerous “safe harbors” that exempt certain actions from the AKS’s scope. *See* 42 U.S.C. § 1320a-7b(b)(3). One such safe harbor exempts remuneration paid by an employer to an employee. *See id.* § 1320a-7b(b)(3)(B). But there is no equivalent safe harbor for payments to independent contractors. Congress authorized the Department of Health and Human Services (HHS) to create additional safe harbors by regulation, *see id.* § 1320a-7b(b)(3)(E), but HHS has pointedly refused to protect commission-based independent contractor arrangements that account for sales volume. As HHS explained in the Federal Register in 1991, the government has “reject[ed] this approach” despite industry urging “because of ... widespread abusive practices by salespersons who are independent contractors,” and who are therefore “not under appropriate supervision and control” like employees are. 56 Fed. Reg. 35,952, 35,981 (July 29, 1991).

VI. Conclusion

For the foregoing reasons, the United States respectfully submits that: (1) proof of FCA liability for claims that arise out of kickbacks does not require a showing that the kickback was the but-for cause of submission of the false claim; (2) “remuneration,” as used in the AKS, can include compensation that is fair market value; (3) provided the requisite intent is met, the AKS prohibits paying sales commissions to independent contractors based on the profitability of sales.¹

¹ If the Court does dismiss Relator’s complaint under Rule 12(b)(6), such dismissal should be without prejudice to the United States. *See, e.g., United States ex rel. Williams v. Bell Helicopter Textron Inc.*, 417 F.3d 450, 455–56 (5th Cir. 2005).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 25, 2024, I electronically submitted the foregoing document with the clerk of the court for the U.S. District Court, Northern District of Texas, using the electronic case filing system and served upon all opposing parties, or their attorneys of record, by electronic delivery on this date.

/s/ Dawn Whalen Theiss

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